

REMARKS

Reconsideration of the above-identified application is requested.

Claims 1-4 and 15 have been rejected under 35 U.S.C. §103(a) over Royce in view of Folkers et al. This rejection is respectfully traversed. Royce discloses the use of a compressible dosage form using polyethylene oxide as a binder. However, Royce does not disclose the use of this binder in the preparation of either water-soluble salts of compounds nor those of fluvastatin. In column 4, lines 44-57 Royce discloses the use of this binder with nearly all known drugs. Then Royce sets out particular drugs and does not mention any of HMG-CoA reductase inhibitors, statins or hyperlipidemic drugs. The only basis for obviousness of the present invention is the statement by Royce that the polyethylene oxide can be used for all drugs without limitation. This is clearly an "obvious to try" basis obviousness, which has been stated to be an improper basis by the Federal Circuit on numerous occasions. Not only is fluvastatin not mentioned but statins and any hyperlipidemic are not mentioned either. Therefore, it would not be suggest to one of skill in the art to use the polyethylene oxide binder for water-soluble salts of fluvastatin based on the teachings of Royce.

Folkers does not cure the deficiencies of Royce. Folkers is mainly concerned with a combination of HMG-CoA reductase inhibitors with coenzyme Q10 to protect against HMG-CoA reductase inhibitor side effects. Folkers does not mention polyethylene oxide binders for formulations.

Accordingly, there is no teaching or suggestion in either reference, either taken alone or in combination, of the present invention. This rejection has, therefore, been traversed and should be withdrawn

Claims 1-4 and 15 have been rejected as being indefinite with respect to the location of the drug. This rejection is respectfully traversed. Applicants respectfully submit that Claim 1 makes it clear that the composition comprises i) a water-soluble salt of fluvastatin and ii) a polymeric matrix in any physical admixture. The comprising language is open-ended so that the drug could be a homogeneous mixture with the matrix or could be partially enveloped by the matrix. Accordingly, this rejection has been traversed and should be withdrawn..

In view of the foregoing, Applicant submits the Application is now in condition for allowance and respectfully requests early notice to that effect.

Respectfully submitted,



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